

### **REMARKS/ARGUMENTS**

Claims 44-77 are pending in this application and these claims are all rejected. In this response claim 47 has been amended to more clearly define applicants' method by introducing into the claim the subject matter previously recited in original claims 48 and 49. The amendments to claim 1, thus, are completely supported by the application as originally filed and entry of the subject amendments is respectfully requested. Claims 48, 49 and 74 are, moreover, canceled herein without prejudice or disclaimer.

New claim 78 is also proposed for addition hereto. The claim is supported by the application as originally filed and thus it raises no issue of new matter.

Entry of the claim amendments and the proposed new claim into the file of the application is respectfully requested. Upon such entry, claims 47, 50-73 and 75-77, as amended, and new claim 78 will be pending in the application for the Examiner's consideration.

#### **Proposed New Claim 78**

Claim 78 is deemed by the applicants to be directed to the same invention as the claims presently under examination. In general, the claims pending in this application are directed to the effect of isomalt as a bifidogenic prebiotic and a butyrogenic substrate. As such, the effect of isomalt is to increase the bifidogenic bacteria in the gastrointestinal tract of a subject upon consumption of the isomalt. This is particularly demonstrated in the written description provided in the present application at p. 7, end of the second paragraph; p. 10, second and third paragraphs; and Examples 1 and 4. Thus, new claim 78 represents only a re-formulation of the claim language of the claims already under examination to focus on the function, as noted above, of isomalt as a bifidogenic prebiotic and a butyrogenic substrate that manifests itself in an increase in the amount of bifidobacteria and butyrate supplied to the gastrointestinal tract of a subject.

In applicants' view, therefore, proposed claim 78 is believed to be directed to the same invention as the Examiner is already examining and thus its entry into the file of the present application and consideration by the Examiner are respectfully solicited.

### **Information Disclosure Statement**

As indicated on p. 2 of the Action, the Examiner has lined through certain entries in the IDS's filed December 14, 2005 and April 3, 2008. The Examiner states that the lined-through entries were listed incompletely on the IDS form.

In response, provided herewith is a new set of IDS forms wherein, *inter alia*, the entries that were lined through on the earlier forms are re-listed in a complete manner. In addition, English-language translations of at least the relevant portions of certain references initially provided in a language other than English are also being provided.

The Examiner is respectfully invited to consider all of the references identified on the forms and to make them of record in the present application.

### **Claim Rejections Under 35 U.S.C. §112**

At pp. 2-3 claim 76 is rejected under 35 U.S.C. §112, second paragraph, as being allegedly indefinite. According to the Office Action, diarrhea is not seen to be an infectious disease and, as such, the provision in claim 76 that the infectious disease of claim 75 is selected from the group including, *inter alia*, diarrheas, is believed by the Examiner to be confusing. This ground of rejection is respectfully traversed.

In response, the Examiner's attention is respectfully directed to the web address of the World Health Organization (WHO), i.e., <http://www.who.int/topics/diarrhoea/en/>. A review of the internet web-site of this renowned organization clearly demonstrates that, according to the World Health Organization, diarrhea is in fact an infectious disease. For the convenience of the Examiner a copy of the home page of the WHO web site is attached to this Amendment.

The Examiner is, thus, respectfully requested to reconsider and withdraw the rejection of claim 76 under 35 U.S.C. §112, second paragraph.

Further to the above, on pp. 3-4 of the Office Action claim 74 is rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement of that statutory section. In response, claim 74 is canceled herein without prejudice or disclaimer. This cancellation thus renders the subject rejection moot and the Examiner is respectfully requested to withdraw the rejection.

### **Claim Rejections Under 35 U.S.C. §102 (b)**

On pp. 5-6 of the Office Action claims 47-53, 60-72 and 77 are rejected under 35 U.S.C. §102(b) for the reasons given over Tangsen et al., The Natural New-Type Sweetening Agent” (“Tangsen”). The rejection is respectfully traversed.

In response to the above-described ground for rejection applicants note that the Tangsen reference merely describes that palatinitol, i.e., isomalt, is a sweetening agent that has a low calorie content, a pure sweet taste and a good flavor. The reference additionally discloses that such palatinitol does not cause tooth decay and/or high glucose and insulin levels after ingestion, and that the metabolites of palatinitol are utilized and fermented by microorganisms in the large intestine to produce small molecular organic acids. There is no disclosure contained in the subject reference, however, that isomalt has a bifidogenic function and, upon consumption, leads to an increase in the proportion of bifidobacteria in the intestinal tract of one consuming the material. At the same time, the claimed mixture also serves as a substrate for the formation of butyric acid in the gastrointestinal tract of a subject. This feature also is not taught in Tangsen. Both of the features noted above, i.e., which are claimed but not disclosed in the cited reference, serve to promote the intestinal health of a subject as well as a healthy metabolism, and can also be used for the treatment of infectious diseases of the intestines.

For the reasons presented above, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §102(b) based on the Tangsen reference as the subject reference does not disclose every element recited in the rejected claims.

Further to the above, on pp. 6-7 claims 47-56, 60-65, 67-73 and 75-77 are rejected under 35 U.S.C. §102 (b) as being allegedly anticipated by U.S. Patent No. 6,139,864 of Dürr et al. (“Dürr”). The rejection is also respectfully traversed.

The cited reference does disclose isomalt mixtures with other saccharides and that such mixtures act as anti-microbially active compounds. Applicants submit, however, that the Dürr patent does not contain any teaching that any of the isomalt-containing mixtures described therein have a bifidogenic or butyrogenic function. Furthermore, the reference additionally fails to disclose the use of such isomalt-containing mixtures to treat bowel disorders or infectious

diseases of the intestine.

Based on the lack of teaching contained in the Dürr reference as outlined above, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §102(b) based on the subject reference.

### **Claim Rejections Under 35 U.S.C. §103**

At pp. 8-9 of the Office Action claims 1-73 (see below) and 75-77 are rejected under 35 U.S.C. §103 over the Tangsen reference as applied to claims 47-53, 60-72 and 77, and further in view of EP 0 904 784. In response, the Examiner is respectfully reminded that only claims 47-77 were pending in this application at the time the present Office Action was issued, i.e., "Use" claims 1-46 were previously canceled in the Preliminary Amendment filed on December 14, 2005. Thus, applicants believe that the rejection was intended to apply to claims 47 - 73 and 75 - 77 and the remarks below reflect this belief. If the Examiner meant something different, however, he is respectfully requested to clarify his position in his next Communication. The rejection - construed as indicated above - is respectfully traversed.

Insofar as the Tangsen reference is concerned, as indicated above in the discussion of the rejection under 35 U.S.C. §102(b) based on the subject reference, Tangsen is viewed as merely describing the characteristics of palatinitol (i.e, isomalt) in that the material is taught to be a sweetening agent which has a low calorie content, a pure sweet taste and a good flavor, which does not cause tooth decay and high insulin and glucose levels after ingestion. Furthermore, as also noted above, the reference additionally discloses that the metabolites produced upon ingestion of such palatinitol are utilized, i.e., fermented, by microorganisms located in the large intestine to produce small molecular organic acids. The reference is entirely lacking, however, in any disclosure which would teach or even suggest to one having an ordinary level of skill in the relevant art that such isomalt has a bifidogenic function as presently claimed. Still further, the reference is additionally lacking in any teaching or suggestion that the consumption of isomalt leads to an increase in the proportion of bifidobacteria in the intestinal tract of a subject.

Applicants are, of course, aware that the rejection in question is based not on Tangsen alone, but on the combination of that reference with EP 0 904 784 (Applicant: N.V. Nutricia).

The subject reference is cited, i.e., as indicated at p. 9 of the Office Action, to supply certain elements not disclosed in Tangsen, i.e., the addition of various micro-organisms to prebiotic/probiotic compositions - such as *Lactobacillus* and *Bifidobacterium*. However the reference does not supply the important teachings, noted above as also not found in Tangsen, i.e., that isomalt has a bifidogenic function (as presently claimed) and/or that the consumption of isomalt leads to an increase in the proportion of bifidobacteria in the intestinal tract of a subject.

Taking the above into account, therefore, the Examiner is respectfully requested to reconsider and withdraw the rejection under 35 U.S.C. §103 based on the combination of Tangsen with the N.V. Nutricia reference.

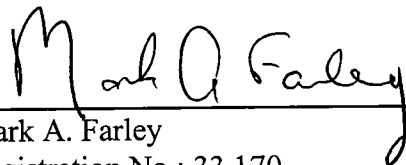
### Summary

Applicants respectfully submit that they believe that the claim amendments and arguments presented above are sufficient to overcome all of the rejections set forth in the present Office Action. The Examiner is, therefore, respectfully requested to reconsider and withdraw the rejections and to issue a Notice of Allowance for all of the pending claims of the application.

THIS CORRESPONDENCE IS BEING  
SUBMITTED ELECTRONICALLY  
THROUGH THE PATENT AND  
TRADEMARK OFFICE EFS FILING  
SYSTEM ON September 10, 2010.

MAF:ck

Respectfully submitted,



Mark A. Farley  
Registration No.: 33,170  
OSTROLENK FABER LLP  
1180 Avenue of the Americas  
New York, New York 10036-8403  
Telephone: (212) 382-0700



عربي  
Español

中文

English

Français

Русский

☒ All WHO ☐ This site only

[Home](#)

[About WHO](#)

[Countries](#)

[Health topics](#)

[Publications](#)

[Data and statistics](#)

[Programmes and projects](#)

[WHO > Health topics > Diarrhoea](#)

## Diarrhoea

Diarrhoea is the passage of 3 or more loose or liquid stools per day, or more frequently than is normal for the individual. It is usually a symptom of gastrointestinal infection, which can be caused by a variety of bacterial, viral and parasitic organisms. Infection is spread through contaminated food or drinking-water, or from person to person as a result of poor hygiene.

Severe diarrhoea leads to fluid loss, and may be life-threatening, particularly in young children and people who are malnourished or have impaired immunity.



### GENERAL INFORMATION

[Diarrhoeal disease](#)

[Food safety and foodborne illness](#)

[Enterohaemorrhagic Escherichia coli \(EHEC\)](#)

[Cholera](#)

### WHO PROGRAMMES AND ACTIVITIES

[Child and Adolescent Health and Development \(CAH\)](#)

[Water, Sanitation and Health \(WSH\)](#)

[Food Safety and Zoonoses \(FOS\)](#)

[Initiative for Vaccine Research \(IVR\)](#)

### TECHNICAL INFORMATION

[Vaccine research: diarrhoeal diseases](#)

[Cholera](#)

[Water-related diseases](#)

[Household water treatment and safe storage](#)

[Global Foodborne Infections Network \(GFN\)](#)

### PUBLICATIONS

[Diarrhoea: why children are still dying and what can be done](#)

[Diarrhoea: child and adolescent health](#)

[Diarrhoea: cholera](#)

### RELATED TOPICS

- [Child health](#)
- [Water](#)
- [Food safety](#)
- [Cholera](#)
- [Travel and health](#)
- [Breastfeeding](#)
- [Vaccines](#)

### KEY WHO INFORMATION

[Director-General](#)  
Director-General and senior management

[Governance of WHO](#)  
WHO Constitution, Executive Board and World Health Assembly

[Media centre](#)  
News, events, fact sheets, multimedia and contacts

[International travel and health](#)  
Publication on travel risks, precautions and vaccination requirements

[World Health Report](#)  
Annual report on global public health and key statistics